

Submitter:
Forge Medical, Inc.

VasoStat™ Hemostasis Device
Premarket Notification: Traditional 510(k)

MAY 29 2013

510(k) Summary

Submitter Name: Forge Medical, Inc

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Date Prepared: 30 April, 2013

Device Trade Name: VasoStat™ Hemostasis Device

Common Name: Vascular compression device

Classification Name: Vascular clamp
Number and: 870.4450
Product Code: DXC

Predicate Devices: RaDAR Vascular Compression Device (Advanced Vascular Dynamics) (DXC): K092503
TR Band (Terumo) (DXC): K070423
VasoStat™ Hemostasis Device (Forge Medical) (NOO): Device Listing (D147574)

Device Description: The VasoStat™ Hemostasis Device is an ergonomic, simple device that is adhered to the patient's skin directly over a percutaneous vascular puncture site and allows the application of adjustable compression to the puncture site to achieve hemostasis. The device is composed of a flexible thermoplastic base that has the ability to conform to the patient's anatomy (e.g.

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lower arm, upper arm, etc.) and is secured to the skin with biocompatible, hypoallergenic adhesive pads. A plunger component passes through the base, applies targeted pressure to the puncture site through a ratcheting mechanism, and can be adjusted with one hand to apply the appropriate pressure necessary to promote hemostasis. VasoStat has the ability to vary the amount of pressure applied to the puncture site to promote hemostasis while minimizing the risk of thrombosis. The device design and materials ensure that the product is comfortable for the patient to wear while their puncture site stops bleeding. Once hemostasis is achieved (in approximately 15 to 45 minutes), the device is easily removed and discarded.

Statement of
Indication for Use

The VasoStat™ Hemostasis Device is indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm, including radial artery catheterization, arterial or venous line removal, hemodialysis, and in patients on anticoagulation therapy.

Summary of
Technological
Characteristics

The VasoStat™ Hemostasis Device is designed to provide local compression to the puncture sites of a dialysis access shunt of a dialysis patient. The device applies uniform pressure to the sites of needle puncture along the dialysis access shunt until hemostasis is achieved. The degree of pressure is designed to stop bleeding without causing blood clots.

A domestic swine model was utilized for in vivo assessment of the VasoStat™ Hemostasis Device in comparison to the Terumo TR Band (predicate device). Vascular sheaths were created in the femoral arteries and veins, and in the jugular veins. The sheaths were removed and either a VasoStat™ Hemostasis Device or a Terumo TR Band placed. Both devices achieved hemostasis in the approximately 5.8 minutes (average). These results demonstrate that the VasoStat™ Hemostasis Device and the predicate device are substantially equivalent.

Biocompatibility testing (per ISO 10993) performed on the device demonstrated, that the VasoStat Hemostasis Device is safe for the indications of use, and was found to be non-cytotoxic, non-reactive and non-sensitizing by ISO Cytotoxicity, ISO Intracutaneous Reactivity and ISO Buehler Sensitization testing, respectively.

Substantial
Equivalence

The VasoStat™ Hemostasis Device is substantially equivalent to the predicates, RaDAR Vascular Compression Device (K092503), the TR Band (K070423), and the VasoStat™ Hemostasis Device (D147574), with respect to technical and design features. The submitted device poses no new questions about safety or effectiveness as compared to the predicate devices.

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Conclusion The information discussed above and presented in the following table demonstrates that the VasoStat™ Hemostasis Device is substantially equivalent to the predicate devices.

Declarations

- This summary includes only information that is also covered in the body of the 510(k).
- This summary does not contain any unsubstantiated labeling claims.
- This summary does not contain any raw data, i.e., contains only summary data.
- This summary does not contain any trade secret or confidential commercial information.
- This summary does not contain any patient identification information.

Summary of Substantial Equivalence

Feature	VasoStat™ Hemostasis Device	RadAR Vascular Compression Device	TR Band	VasoStat™ Hemostasis Device
510(k) Number	K123041	K092503	K070423	D147574
Class	II	II	II	I (Exempt)
Classification	Vascular clamp	Vascular clamp	Vascular clamp	Clamp, Dialysis arm
Regulation	870.4450	870.4450	870.4450	876.5540
Product Code(s)	DXC	DXC	DXC	NOO
Indications for Use	...indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm, including radial artery catheterization, arterial or venous line removal, hemodialysis, and in patients on anticoagulation therapy.	...indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm, including radial artery catheterization, arterial or venous line removal, hemodialysis, and in patients on anticoagulation therapy.	...is a compression device to assist hemostasis of the radial artery after a transradial procedure.	...to temporarily apply puncture site compression and, aid in obtaining puncture site hemostasis, following the removal of dialysis needles.
Mode of Action	Compression	Compression	Compression	Compression
In Vivo Performance	Hemostatic	Not Tested	Hemostatic	Hemostatic
Composition	Molded Polypropylene/Polyethylene Foam/Acrylic Adhesive	Not Available	Plastic	Molded Polypropylene/Polyethylene Foam/Acrylic Adhesive
Biocompatibility	ISO 10993 – Part 5 ISO 10993 – Part 10	Established biocompatible materials	ISO 10993 – Part 5 ISO 10993 – Part 10	ISO 10993 – Part 5 ISO 10993 – Part 10



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2013

Forge Medical, Inc.
c/o Mr. Mason Diamond
150 Levinberg Lane
Wayne, NJ 07470

Re: K123041

Trade/Device Name: VasoStat Hemostasis Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: April 10, 2013
Received: April 12, 2013

Dear Mr. Mason Diamond:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate

commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K123041

Device Name: VasoStat™ Hemostasis Device

Indications for Use:

The VasoStat™ Hemostasis Device is indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm, including radial artery catheterization, arterial or venous line removal, hemodialysis, and in patients on anticoagulation therapy.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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